

P A T E N T

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Justin M. Crank Confirmation No.: 2850  
 Serial No.: 10/647,613 Examiner: J. Hoekstra  
 Filing Date: August 25, 2003 Group Art Unit: 3736  
 Docket No.: 1001.1686101 Customer No.: 28075  
 For: ELONGATED INTRA-LUMENAL MEDICAL DEVICE

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PRE-APPEAL BRIEF REQUEST FOR REVIEWCERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. §1.8 (1)(B))

I hereby certify that this correspondence is being transmitted by facsimile to the United States Patent and Trademark Office at 571-273-8300 on the date shown below.

Karleen L. Boekley

Type or print name of person signing certification

Karleen L. Boekley  
Signature

September 22, 2006

Date

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

Justin M. Crank

By his Attorney,

David M. Crompton

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Date: 9/22/06

Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

UNITED STATES PATENT AND TRADEMARK OFFICE

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PRE-APPEAL BRIEF REQUEST FOR REVIEW ATTACHMENTCERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. §1.8 (1)(i)(B))

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Kathleen L. Boekley  
Type or print name of person signing certification

Kathleen L. Boekley  
Signature

September 22, 2006  
Date

Dear Sir:

Applicant has carefully reviewed the Final Office Action dated June 21, 2006 and the Advisory Action dated September 1, 2006. Currently claims 1-32 are pending in the application, wherein claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29 and 32 have been rejected and the remainder of the claims have been withdrawn from consideration consequent an Examiner-induced requirement for restriction. Applicant hereby requests a pre-appeal conference and files this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

The Examiner maintains the rejection of the claims over the combination of Samson et al., U.S. Patent No. 5,827,201, and Dobson, U.S. Patent No. 5,724,989. It seems apparent that the Examiner has failed to appreciate the substance of the arguments presented in the Response After Final, dated August 18, 2006, which are summarized below, and thus has not correctly applied the legal standard for examination. Namely, the combination at least fails to teach each and every limitation recited in the claims.

Claim 1 recites:

1. A medical device comprising:  
a coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire, the wire comprising:
  - (a) a cross-section with a centroid;
  - (b) a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil; and
  - (c) a moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil, wherein the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater

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than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

Claim 10, which is directed to a medical guidewire, includes similar limitations of a wire forming a coil.

At page 2 of the Final Office Action, the Examiner erroneously states that a composite coil of two different materials wherein the outer material has a larger Young's modulus than that of the inner material "dictates that the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil." Applicant respectfully disagrees with this statement.

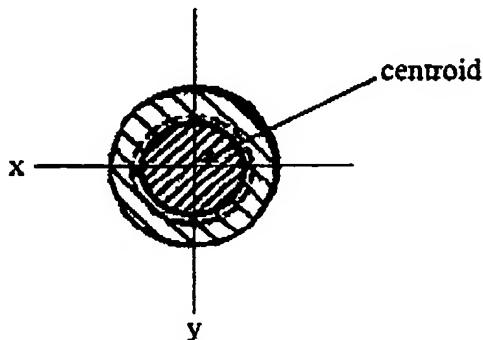
Applicant notes the moment of inertia as described in the current application, which is otherwise known as the second moment of area, is a property of a shape which may be used to determine the resistance to bending and deflection of the shape. In general, a shape is more efficient to resist bending when the greater part of its mass is as far as possible from its centroid. This is evidenced by the equations provided at page 13, line 7 of the current application.

The mere observation that an outer material of a member has a larger Young's modulus than that of an inner material does not, in and of itself, dictate the relationship of the moments of inertia of the member. Indeed, the multi-layer wire of the spring 14 taught in Dobson fails to exhibit the claim limitations that the wire forming the coil has a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil which is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

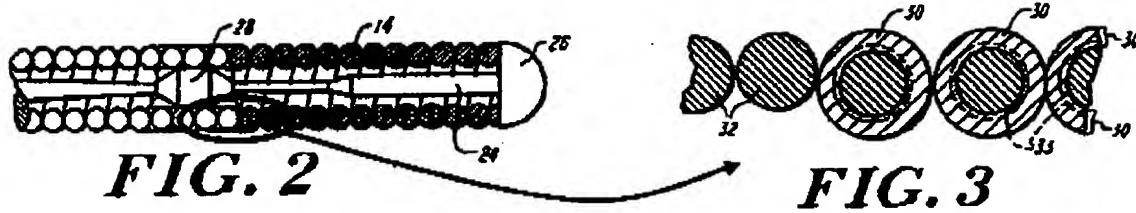
The ratio of the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis to the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of a member would be 1:1 in a member having a bi-axially symmetrical cross-section. This is also evidenced by the equations provided at line 7 of page 13 of the current application. In order to change the ratio, more material would need to be moved away from the x-axis (longitudinal axis) without moving the same or greater amount of material away from the y-axis (radial axis), or vice versa.

The cross-section of the wire of the spring 14 disclosed in Dobson is reproduced below with the inclusion of a longitudinal axis of the spring (axis x) running through the centroid and a radial axis of the spring (axis y) running through the centroid. The Examiner's statement in the Advisory Action that "the longitudinal axis was considered to be through the centroid and along guidewire's length as opposed to the reproduction (sic) of Dobson presented (sic) in the request for reconsideration" is noted. See Advisory Action, September 1, 2006, at page 2. Indeed, consistent with the Examiner's determination, the axis x added to the figure of Dobson reproduced below is an axis running through the centroid and

along the guidewire's length (i.e., parallel to the longitudinal axis of the spring 14), consistent with the teachings of Dobson.



In support of this assertion, Figures 2 and 3 of Dobson, are reproduced in their entirety below.



The portion of the spring 14 encircled in Figure 2 is representative to the portion of the spring 14 illustrated in more detail in Figure 3, showing cross-sections of adjacent turns of the wire forming the spring 14. Concerning that illustrated in Figures 2 and 3, Dobson states:

According to the present invention, the wire forming the coils in the distal approximately 2.5 cm. (about 1 inch) of spring 14 includes an annular, circumferentially surrounding layer 30 of radiopaque material having an outer diameter not more than about 0.002 in. (about 0.05 mm.) greater than that of the stainless steel central portion 32 of spring 14 on which the radiopaque material is deposited. In FIG. 2, the spring coils which include layer 30 are cross-hatched; FIG. 3, which is greatly enlarged, shows both annular layer 30 and the central portion 32 of the stainless steel wire that the layer 30 circumferentially surrounds.

Dobson, at column 3, lines 26-36. Thus, axis x included in the illustrative figure reproduced above is indeed an axis running through the centroid and parallel to the longitudinal axis of the spring 14 (i.e., along the guidewire's length), consistent with the Examiner's understanding of the claims.

The dimensional characteristics and material distribution of the cross-section the wire of the spring 14 illustrated in Figure 3 of Dobson, which is bi-axially symmetrical (e.g., symmetrical about the x and y axes), would result in a 1:1 ratio. Namely, as the cross-section of both the inner material 32 and the outer material 30 of the wire is circular in nature, an equal amount of material would be located at all

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radial locations from the center of the cross-section (which also would be the centroid in this case). Using the equations which are provided at line 7 of page 13 of the present application, one of skill in the art would conclude that the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis (axis x) of the spring 14 would be equal to the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis (axis y) of the spring 14. Thus, Dobson does not exhibit the claim limitations that the wire forming the coil has a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil which is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

It follows that the Examiner's assertion that a composite coil of two different materials wherein the outer material has a larger Young's modulus than that of the inner material "dictates that the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil" (emphasis added) is clearly not a true statement in all instances, including the instance disclosed in Dobson.

For at least the reasons stated above, claims 1 and 10, as well as claims 2, 5, 7, 9, 11, 14, 16 and 18 which depend from one of claims 1 and 10, are believed patentable over the cited combination. Neither Samson, nor Dobson, individually or in combination, disclose that which is currently claimed. Withdrawal of the rejection is respectfully requested.

Regarding the rejection of claims 19 and 26, the Examiner states that the Young's modulus of tungsten carbide ranges between 450-650 GPa and the Young's modulus of Nitinol ranges between 28-75 GPa. Applicant respectfully asserts these values are irrelevant to the spring 14 taught in Dobson. Dobson teaches a spring 14 formed of a stainless steel core material and a layer of gold deposited on the stainless steel core. See Dobson, Abstract.

For at least the reasons stated above, withdrawal of the rejection of claims 19 and 26 as well as claims 21, 22, 25, 28, 29 and 32, which depend from one of claims 19 and 26, is respectfully requested.

Regarding the rejection of claims 2, 9, 11, 18, 21, 22, 28 and 29, the Examiner states with reference to lines 54-58 of column 9 that "Samson et al discloses a wire of polygonal and rectangular cross section." Final Office Action, June 21, 2006, page 3. Applicant respectfully disagrees with the Examiner's suggestion that this passage teaches that which is claimed in claims 2, 9, 11, 18, 21, 22, 28 and 29.

Claims 2, 9, 11, 18, 21, 22, 28 and 29 each further define the cross-section of the wire forming the coil as claimed. In the rejection, the Examiner equated the coil 148, 188 taught in Samson with the claimed coil. However, the cited passage of Samson is not describing either the coil 148 or the coil 188.

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Instead, the cited passage of Samson is directed to metallic ribbons forming the braid, an entirely different component of the device taught in Samson. Indeed, the cited passage is included in the portion of Samson subtitled "Braids". See Samson, column 8, line 61. Samson expressly describes that the braids are constructed of ribbons. See Samson, column 9, line 30 through column 10, line 19. It is these ribbons, which form the braid, that are described in detail at lines 54-58 of column 9. In carefully reviewing the teachings of Samson, Samson, as well as Dobson, only discloses the use of a coil having a circular cross-section.

For at least this reason, Applicant asserts the identified passage of Samson fails to meet the limitations recited in claims 2, 9, 11, 18, 21, 22, 28 and 29. Furthermore, Dobson fails to remedy the shortcomings of Samson. Thus, the cited combination fails to teach at least these limitations of the claims. Withdrawal of the rejection is respectfully requested.

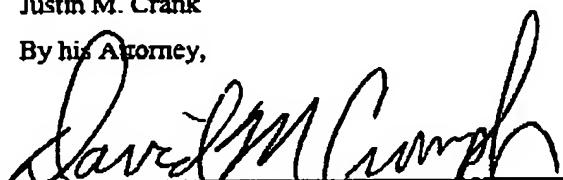
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Date: 9/22/06

Respectfully submitted,

Justin M. Crank

By his Attorney,



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